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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/518,297 | 03/03/2000 | Moon Young Lim | 4600-0130.30 | 5390 |

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EXAMINER

KAM, CHIH MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

19

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,297

Applicant(s)

LIM ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 11-17, 19 and 27-30 is/are rejected.
- 7) ☒ Claim(s) 6, 9, 10 and 21-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The finality of previous Office Action is withdrawn due to a new ground rejection.

Status of the Claims

2. Claims 1-19 and 21-30 are pending.

Applicants' response filed January 16, 2003 (Paper No. 17) is acknowledged, and applicants' response has been fully considered.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1-19 and 21-30, under 35 U.S.C.112, second paragraph, regarding the term "a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound", is withdrawn in view of applicants' response at pages 1-2 in Paper No. 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 12 are indefinite because the claim cites part (v) while the independent claim (claim 1 or 11) cites parts (i)-(iii), it is not clear what part (iv) is. See also claim 19.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7, 8, 11, 13-17 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein *et al.* (U. S. Patent 5,527,690).

Goldstein *et al.* teaches a sterol regulatory element (SRE) binding proteins (SREBP) which are involved in the regulation of genes in cholesterol metabolism that are under the control of SRE-1 (column 1, lines 17-26; column 2, line 53-58). The reference indicates a recombinant plasmid including a reporter gene, preferably a CAT gene or luciferase gene under the transcriptional control of a functional SRE-1 sequence, wherein the SRE-1 sequences may be mutants but transcriptionally-functional (column 3, lines 29-48; Fig. 1), and SREBP-1 (acts as not only as a transcriptional regulatory protein but also as a DNA binding compound) binds SRE-1 DNA sequences to promote transcription and gene expression (column 13, line 19-column 14, line 14; claim 1). The reference also teach co-introduction of SRE-1 mediated reporter genes along with SREBP encoding genes into host cells (column 14, lines 32-34; Example 3; claims 2, 5, 7, 8 and 11). The SREBP-1 can be a native protein or recombinantly made (column 3, lines 50-54; claims 3 and 4). The plasmid constructs contain multiple copies (e.g., two copies of repeat 2+3) of compound binding sequences/or transcriptional regulatory protein DNA response elements and the compound binding sequence/or transcriptional regulatory protein DNA response element (repeat 2 or 3) has 16 nucleotide (column 6, lines 25-

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39; Fig. 1; claims 13-15, 27 and 29). The plasmid is then introduced into a recombinant host cell such as monkey CV-1 cell (column 14, lines 2-14; claims 16, 17, 28, 30), and the host cell is cultured under conditions to allow expression of the reporter gene.

6. Claims 6, 9, 10 and 21-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. Claims 1-5, 7, 8, 11-17, 19 and 27-30 are rejected, and claims 6, 9, 10 and 21-26 are objected. It appears claim 18 is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Christopher S. F. Low

March 20, 2003

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